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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)  SYN-064C
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on <u>August 7, 2009</u></p> <p>Signature <u>Rebecca A. Tie</u></p> <p>Typed or printed name <u>Rebecca A. Tie</u></p>		<p>Application Number 10/010,246</p> <p>Filed 12/06/2001</p> <p>First Named Inventor Robert Sixto, Jr., et al.</p> <p>Art Unit 3773</p> <p>Examiner Darwin P. Erezo</p>

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- applicant/inventor.
- assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)
- attorney or agent of record. 62095  
Registration number \_\_\_\_\_
- attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

Rebecca A. Tie  
Signature  
\_\_\_\_\_  
Rebecca A. Tie  
\_\_\_\_\_  
Typed or printed name  
\_\_\_\_\_  
(954) 704-1599  
\_\_\_\_\_  
Telephone number  
\_\_\_\_\_  
August 7, 2009  
Date  
\_\_\_\_\_

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  
Submit multiple forms if more than one signature is required, see below\*.

<input type="checkbox"/>	*Total of _____ forms are submitted.
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This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**PRE-APPEAL BRIEF**

**TITLE OF INVENTION:**

**SURGICAL CLIPS PARTICULARLY USEFUL IN THE  
ENDOLUMINAL TREATMENT OF GASTROESOPHAGEAL  
REFLUX DISEASE (GERD)**

Appl. No.: 10/010,246  
Applicant: Robert Sixto, Jr., et al.  
Filed: 12/06/2001  
TC/A.U.: 3773  
Examiner: Darwin P. Erez  
Confirmation No.: 5866  
Docket No.: SYN-064C

**Mayback  
& Hoffman, P.A.  
5722 S. Flamingo Rd. #232  
Ft. Lauderdale, FL 33330  
Office: 954.704.1599  
Fax: 954.704.1588**

The following remarks are submitted to be considered along with Appellants' Notice of Appeal. U.S. Patent No. 5,620,452 to *Yoon* (hereinafter "Yoon"), cited by the Examiner, does not anticipate each and every element of the presently claimed invention as is required under 35 U.S.C. §102(b).

**CLAIM REJECTIONS UNDER 35 U.S.C. §102(b)**

A brief history of the present application includes Appellants' response of July 7, 2009 (hereinafter "Response"), which was filed in response to the final Office action dated May 7, 2009 (hereinafter "Final Office Action"), whereby the Examiner maintained the rejection of claims 1, 2, 4, 17, 18, 21-23, 25 and 32 as being anticipated by *Yoon*. In the Response, Appellants, not for the first time, provided a comprehensive argument that *Yoon* does not describe a surgical clip having a bridge that connects a first arm and a second arm to form a **substantially static** U-shaped structure whereby the U-shape **is retained prior to, throughout and subsequent to application** of the clip, which are required elements of each independent claim (i.e. claims 1, 17, 21, 22 and 32).

The term "static" is defined as "showing little change." *See Merriam-Webster's Online Dictionary* (available at [www.merriam-webster.com](http://www.merriam-webster.com)). Based on this ordinary definition and the detailed description in the specification of the meaning of the term "static" as it is used in the claims, Appellants respectfully believe that it should have been clear throughout the examination of the present application that the term "substantially static" means that in general, the U-shaped structure of the bridge consistently stays substantially the same and shows little change regardless of how or when it is being used. Prior to Appellants' Response, in an effort to clarify that the bridge is static in nature, Appellants amended claims 1, 17, 21, 22 and 32 to specifically state that the U-shape of the bridge "is retained prior to, throughout and subsequent to application" of the clip. However, in the Final Office Action, the Examiner appeared to still misunderstand that the bridge is static in nature and maintained the claim rejections in view of *Yoon*, stating that the clip in *Yoon* is "fully capable of retaining its substantially U-shaped configuration prior to, throughout, and subsequent to application."

In response, in an effort to even further clarify the static nature of the bridge, Appellants amended claims 1, 17, 21, 22 and 32 to specifically state that the bridge retains substantially the "same initial" U-shaped structure prior to, throughout, and subsequent to application of the clip. In the July 21, 2009 Advisory Action, the Examiner refused to enter the amendment on the basis that it changes the scope of the claims thereby requiring a new search. Appellants respectfully disagree with the Examiner's conclusion. Just by Appellants' use of the term "static" alone, prior to these amendments, the Examiner's prior search should have already encompassed the idea that the bridge maintains the

same initial U-shape prior to, throughout and subsequent to the application of the clip because if it didn't, it would no longer be static. If the Examiner read into the claims additional, unstated limitations, such that the bridge changes shape during its application or retains a different U-shape than it originally had such that it loses its static nature somewhere along the line, that is an impermissible action and Appellants should not be required to enter into another round of examination as a result. As that suggested amendment has not been entered, the claim language existing prior to this suggested amendment remains for review on appeal.

## I. THE PRESENT INVENTION

As was set forth in the Response and throughout the present application, Appellants' invention concerns a surgical clip inserted by a clip applier after the clip applier jaws grasp and puncture the invaginated fundus. *See, e.g.*, pp. 19-21 of the application as originally filed. A short description of the clipping process is believed to be helpful. First, the jaws of the clip applier grasp and puncture invaginated tissue. *Id.* Then, while the jaws remain in this grasp, the clip is advanced through channels in the respective jaws and the piercing portions of the arms are caused to slide over the tissue for a distance. *Id.* These portions remain straight until the piercing end hits the respective anvil and begins to curve in a circular manner. *Id.* Throughout this clipping process, the jaws guide and hold the bridge and arms in place. *Id.* In this process, *only* the retainer portion of the surgical clip is plastically deformed to affix the clip to the fundus. *Id.*

The claims, as written, provide that a property of the connecting bridge is that its stiffness retains the two parallel arms in the same initial U-shaped form **prior to, throughout, and subsequent to** application. *Id.*, page 23. The bridge secures the arm elements in a **substantially static** position throughout the entire application, an orientation that keeps pressure upon the tissue therebetween. It is only the deformable retainer at the end of one or both of the arms that is/are designed to deform plastically. The bridge does not just retain a U-shaped structure prior to, throughout, and subsequent to application, but it also retains substantially the same initial U-shaped structure prior to, throughout, and subsequent to application such that the shape and diameter of the U-shape does not change in any relevant way.

## II. THE DEVICE IN YOON

A single embodiment of the clip in *Yoon* could be said to resemble a U-shaped structure. But that is where the similarity ends. As shown in FIG. 10, staples 40 mounted on the upper and lower arms 16 and 18 are in opposition to corresponding apertures 36 formed in the lower and upper arms 18 and 16. *Yoon*, col. 4, lines 42-46. These corresponding areas 36 and 40 show that the upper and lower

arms are **designed to meet each other or at least approach each other during application of the clip**. If the arms were moved to where staples 40 were at least 3.14 times the distance between the arms when the arms are substantially parallel (as is recited in claims 1, 17 and 22 of the present application), the bridge section of *Yoon* would no longer resemble a U-shape, but would be a V-shape, as is shown in all of the other illustrated embodiments of *Yoon*. If the clip in *Yoon* must be manipulated to meet this recitation of the claims of the present application, then, by definition, it cannot also be “**a substantially static U-shaped structure**,” as the claims of the present application also recite. In addition, the embodiment shown in FIG. 10 of *Yoon* is described as having “plastically shaped or deformed legs” (*Yoon*, col. 4, lines 49-59) – a configuration that is in direct opposition to the invention, which has “a first arm...a second arm...and a bridge connecting said first and second arms to form a **substantially static** U-shaped structure retaining the shape prior to, throughout, and subsequent to application” as recited in the independent claims of the present application.

Furthermore, on pages 2 and 4 of the Final Office Action, the Examiner notes that “the amount of separation between the two arms merely depends on the amount of force used to press the arms together” and “the shape of the U-shaped structure is merely dependent upon the manipulation of the clip.” Thus, the Examiner acknowledges that the clip in *Yoon* is **not static**. The arm separation is dependent upon the force used to press the arms together and the clip must be **manipulated** in order to form a U-shaped structure. Therefore, the bridge of the clip in *Yoon* does not connect first and second arms to form a **substantially static** U-shaped structure, rather it is a dynamically changing device. Based on the Examiner’s interpretation alone, it is clear that *Yoon* discloses a clip **that only functions if the arms are moved together during normal operation (i.e., they are deformable, non-static) so that the apertures 36 and staple 40 intersect with each other**. In stark contrast, the arms of the clip of the present invention remain “**substantially static**” prior to, throughout, and subsequent to application. Also, the clip in *Yoon* would not function to allow tissue in between the arms if the staples were “at least at least 3.14 times the distance between the arms when the arms are substantially parallel.”

Despite having acknowledged the above non-static characteristics of the clip in *Yoon*, the Examiner concluded that the clip “merely has to have the capability of being applied to a tissue while maintaining the original ‘U-shaped structure’ of the undeployed clip” and identified FIG. 13 as depicting the clip being attached to tissue while maintaining the same U-shaped structure shown in the undeployed clip in FIG. 12. *See* Final Office Action, page 4. In addition to the Examiner’s conclusion that a new search is required, Appellants also respectfully disagree with the Examiner’s line of

reasoning in support of the §102(b) rejection as it is in clear error in a number of respects and accordingly, the rejection should be withdrawn.

### **III. THE EXAMINER HAS NOT SATISFIED THE REQUISITE BURDEN IN MAKING THE REJECTION UNDER 35 U.S.C. §102(b)**

A rejection under 35 U.S.C. §102(b) is proper “only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (emphasis added); MPEP § 2131. The elements of a surgical clip having a bridge that connects a first arm and a second arm to form a substantially static U-shaped structure whereby the U-shape is retained prior to, throughout and subsequent to application of the clip is clearly not found in *Yoon*. Accordingly, *Yoon* does not anticipate independent claims 1 to 7, 32, and/or 33. By the clear language of the statute, it is not sufficient to simply state that the device disclosed in the prior art is somehow “capable” of performing a claimed element in order to overcome the fact that the claimed element is strictly not found in the prior art reference whatsoever. MPEP § 2112.

If it is the Examiner’s position that, although the prior art reference is silent as to the claimed element, the claimed element is an inherent characteristic of the prior art device, the Examiner must supply “extrinsic evidence … [to] make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991); MPEP §§2131.01, 2112. Simply put, the Examiner is required to: (1) provide extrinsic evidence that (2) shows that the missing claim element is necessarily present in the prior art device. Here, there has been no submission of extrinsic evidence which forces only one conclusion -- the instant rejection must be overturned.

With respect to the phrase “necessarily present,” *In re Rijckaer* provides: “[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993) (emphasis added); MPEP §2112. “Inherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.” *Trintec Industries, Inc. v. Top-U.S.A Corporation*, 295 F.3d 1292, 1295 (Fed. Cir. 2002), *citing*, *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (“Inherency does not embrace probabilities or possibilities.”) “… [A]n anticipatory inherent feature or result must be consistent, necessary, and inevitable …” *Chisum on Patents*, § 3.03[2][b], *citing*, *Trintec*, 295 F.3d at 1297. “A reference includes an inherent characteristic if that characteristic is the ‘natural result’ flowing from the

reference's explicitly explicated limitations." *Id.*, citing, *Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1376 (Fed. Cir. 2001).

In an effort to support the assumption that the clip in *Yoon* is merely capable of maintaining the original "U-shaped structure" of the undeployed clip," the Examiner points to FIG. 13 of *Yoon* and concludes that it depicts the clip being attached to tissue while maintaining the same U-shaped structure of the undeployed clip in FIG. 12. This argument fails as FIG. 13 illustrates only one intermediate step in the overall application of the clip. As described in *Yoon*, FIGS. 13 through 15 are side views illustrating use of the clip. *Yoon*, col. 2, lines 64-65; col. 5, lines 27-28. In FIG. 13, tissue is positioned between arms 16 and 18 of the clip with staple legs 50 retracted. The clip 10 is compressed thereby causing the tissue penetrating legs 50 to be driven through openings in the arms and into the tissue. *Id.*, at col. 5, lines 27-47. In FIG. 14, **further compression** is what causes the cross-members 48 to abut respective outer surfaces of arms 16 and 18 as the arms are moved towards one another against the tissue. *Id.* As is clearly shown in FIG. 14, the bridge 14 is **not static** and does not maintain the same shape shown in FIGS. 12 and 13 as the arms are compressed towards one another (i.e., it is not static "throughout" application). In FIG. 15, once the arms 16 and 18 have been compressed together far enough such that they are separated by a distance somewhat less than the length the tissue penetrating legs 50, the legs 50 are able to pass through apertures 36 in the opposed arm and, then, are in a state to be bent around the other side to lock the arms together without distal ends of the arms being coupled. *Id.* As is clearly shown in FIG. 15, although the bridge appears to have returned to a U-shape, the diameter of the U-shape has significantly decreased from the diameter shown in FIG. 12 so that the arms can be locked. Without the ability to change and deform the shape and diameter of bridge 14 in a non-static way, the clip in *Yoon* **could not be attached to the tissue and function as intended**. Therefore, it is not accurate to simply conclude that the clip in *Yoon* must naturally, necessarily and inevitably be capable of maintaining a static U-shaped structure. *Yoon* explicitly describes the non-static movement and compression of the arms of the clip so that the arms may necessarily be locked.

In view of the remarks and arguments given above, *Yoon* does not anticipate each and every element of the presently claimed invention. Accordingly, claims 1, 2, 4, 17, 18, 21-23, 25, and 32 are allowable and the Examiner's rejections under 35 U.S.C. § 102(b) should be reversed. In addition, independent claims 1 and 22 are distinguished over *Yoon*. Since dependent claims contain all the limitations of the independent claims, claims 3, 5-10, 24, 26, 27, and 28-31 distinguished over *Yoon*, as well. Thus, all pending claims are in condition for allowance without the need for a new search.

Respectfully submitted,

Date: August 7, 2009

By:

Rebecca A. Tie  
Rebecca A. Tie, Reg. No. 62,095  
Attorney for Appellants